



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,136	10/27/2003	Gerhard Bienhaus	18583-US1	3248
22829 7590 12/12/2007 ROCHE MOLECULAR SYSTEMS INC PATENT LAW DEPARTMENT 1145 ATLANTIC AVENUE ALAMEDA, CA 94501			EXAMINER RAMILLANO, LORE JANET	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/694,136

Applicant(s)

BIENHAUS ET AL.

Examiner

Lore Ramillano

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/27/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/485144.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Applicant's reply filed on 10/1/07 is acknowledged. Claims 1-13 are pending in the application. Claims 8-13 are withdrawn. Claims 1-7 are under examination.

Election/Restrictions

2. Applicant's election without traverse of claims 1-7 (Group I) in the reply filed on 10/1/07 is acknowledged.
3. Claims 8-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/1/07.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/485144, filed on 10/2/00.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 2/17/04 is acknowledged. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is rejected because the language, "the caps of the matrix unit are in the leaned-to position," does not appear to clearly claim the subject matter of the invention. Does applicant intend to claim that the *matrix vessels* and caps of the matrix unit are in the leaned-to position?

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1-3 and 6-7** are rejected under 35 U.S.C. 102(b) as being anticipated by Uematsu et al. ("Uematsu," US 5538849).

Uematsu teaches a process for isolating a purified biological material comprising the following steps: a) placing biological materials in separate lysis vessels of a lysis unit comprising two or several lysis vessels in a predetermined geometric arrangement, b) adding lysis liquids to the biological materials in the lysis vessels, c) transferring the liquids in the lysis vessels into a matrix unit containing matrix vessels with outlet openings whose number corresponds to the number of lysis vessels and a matrix is located in each of the matrix vessels to which the biological material to be purified binds, d) extracting (i.e. by centrifugation) the liquids in the matrix vessels through the outlet openings during which the liquids flow through the matrices, e) placing the matrix unit on a collecting unit with collecting vessels which are

arranged such that at least the outlet openings of the matrix vessels extend into the collecting vessels, f) filling the matrix vessels with elution fluid, g) extracting the elution fluids from the matrix vessels through their outlet openings during which the elution fluids flow through the matrices and the elution fluids which are enriched with biological material are collected in the collecting vessels. (i.e. figs. 1-6 and 15, column 5, line 10 to column 9, line 11, column 16, lines 51-57).

Uematsu further teaches the following: the collecting unit is closed by a closure unit after removing the matrix unit (i.e. 28).

Uematsu further teaches a process as comprising the steps: a) storing data which identify a biological sample, b) allocating the data relating to the biological sample to data which identify the lysis unit as well as the position of the lysis vessel within the lysis unit into which the sample is added, c) allocating data which identify the matrix unit into which the lysis liquids are added to data which identify the lysis unit, d) allocating data which identify the collecting unit in which the elution liquid from the matrix unit is collected; and the liquids are transferred from the lysis unit into the matrix unit by removing liquid from a lysis vessel and adding it to the matrix vessel of the matrix unit that is in a corresponding position. (i.e. column 5, lines 18 to column 7, line 23).

10. **Claims 1 and 6-7** are rejected under 35 U.S.C. 102(b) as being anticipated by Fujishiro et al. ("Fujishiro," US 5645723).

Fujishiro teaches a process for isolating a purified biological material comprising the following steps: a) placing biological materials in separate lysis vessels of a lysis unit comprising two or several lysis vessels in a predetermined geometric arrangement,

b) adding lysis liquids to the biological materials in the lysis vessels, c) transferring the liquids in the lysis vessels into a matrix unit containing matrix vessels with outlet openings whose number corresponds to the number of lysis vessels and a matrix is located in each of the matrix vessels to which the biological material to be purified binds, d) extracting the liquids in the matrix vessels through the outlet openings during which the liquids flow through the matrices, e) placing the matrix unit on a collecting unit with collecting vessels which are arranged such that at least the outlet openings of the matrix vessels extend into the collecting vessels, f) filling the matrix vessels with elution fluid, g) extracting the elution fluids from the matrix vessels through their outlet openings during which the elution fluids flow through the matrices and the elution fluids which are enriched with biological material are collected in the collecting vessels. (i.e. figs. 2-8, column 2, line 58 to column 8, line 48).

Fujishiro further teaches a process as comprising the steps: a) storing data which identify a biological sample, b) allocating the data relating to the biological sample to data which identify the lysis unit as well as the position of the lysis vessel within the lysis unit into which the sample is added, c) allocating data which identify the matrix unit into which the lysis liquids are added to data which identify the lysis unit, d) allocating data which identify the collecting unit in which the elution liquid from the matrix unit is collected; and the liquids are transferred from the lysis unit into the matrix unit by removing liquid from a lysis vessel and adding it to the matrix vessel of the matrix unit that is in a corresponding position. (i.e. figs. 2-8, column 2, line 58 to column 8, line 48).

11. **Claims 1 and 6-7** are rejected under 35 U.S.C. 102(b) as being anticipated by Bienhaus et al. ("Bienhaus," WO 96/31781, translated by www.worldlingo.com).

Bienhaus teaches a process for isolating a purified biological material comprising the following steps: a) placing biological materials in separate lysis vessels of a lysis unit comprising two or several lysis vessels in a predetermined geometric arrangement, b) adding lysis liquids to the biological materials in the lysis vessels, c) transferring the liquids in the lysis vessels into a matrix unit containing matrix vessels with outlet openings whose number corresponds to the number of lysis vessels and a matrix is located in each of the matrix vessels to which the biological material to be purified binds, d) extracting the liquids in the matrix vessels through the outlet openings during which the liquids flow through the matrices, e) placing the matrix unit on a collecting unit with collecting vessels which are arranged such that at least the outlet openings of the matrix vessels extend into the collecting vessels, f) filling the matrix vessels with elution fluid, g) extracting the elution fluids from the matrix vessels through their outlet openings during which the elution fluids flow through the matrices and the elution fluids which are enriched with biological material are collected in the collecting vessels. (i.e. p. 6-8 of translation).

Bienhaus further teaches a process as comprising the steps: a) storing data which identify a biological sample, b) allocating the data relating to the biological sample to data which identify the lysis unit as well as the position of the lysis vessel within the lysis unit into which the sample is added, c) allocating data which identify the matrix unit into which the lysis liquids are added to data which identify the lysis unit, d) allocating data which identify the collecting unit in which the elution liquid from the matrix unit is collected; and the liquids are transferred from the lysis unit into the matrix unit by removing liquid from a lysis vessel and adding it to the matrix vessel of the matrix unit that is in a corresponding position. (i.e. p. 6-8 of translation).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. **Claims 1-2** are rejected under 35 U.S.C. 103(a) as being unpatentable over Acuff (US 4142858).

Acuff teaches a process for isolating a purified biological material comprising the following steps: a) placing biological materials in separate lysis vessels of a lysis unit comprising two or several lysis vessels in a predetermined geometric arrangement, b) adding lysis liquids to the biological materials in the lysis vessels, c) transferring the liquids in the lysis vessels into a matrix unit containing matrix vessels with outlet openings whose number corresponds to the number of lysis vessels and a matrix is located in each of the matrix vessels to which the biological material to be purified binds, d) extracting (i.e. by centrifugation) the liquids in the matrix vessels through the outlet openings during which the liquids flow through the matrices, e) placing the matrix unit on a collecting unit with collecting vessels which are arranged such that at least the outlet openings of the matrix vessels extend into the collecting vessels, f) filling the matrix vessels with elution fluid, g) extracting the elution fluids from the matrix vessels through their outlet openings during which the elution fluids flow through the matrices and the elution fluids which are enriched with biological material are collected in the collecting vessels. (i.e. fig. 1, column 4, line 16 to column 6, line 63).

As to the plurality of lysis vessels, it has been held that mere duplication of parts has no patentable significance unless new and unexpected result is produced. *In re Harza*, 124 USPQ 378. Furthermore, it would have been obvious to a person of ordinary skill in the art to modify Acuff's method by utilizing a plurality of lysis vessels rather than one lysis vessel at a time to perform the lysis step since it would be desirable to perform multiple tests simultaneously, which would produce many results within a shorter time frame.

16. **Claims 4-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Uematsu over Mochida et al. ("Mochida," US 4479720).

The teachings of Uematsu are shown above. Uematsu does not specifically teach that the other lysis vessels of the lysis unit are leaned-to or closed and that the caps of the matrix unit are in the leaned-to position.

Mochida teaches an apparatus for rotating reaction vessels in an inclined posture comprising a plate, means for rotatably supporting the plate, means for rotating the plate at a predetermined speed, a plurality of reaction vessel holders, and means for rotating the reaction vessel holders. It would have been obvious to a person of ordinary skill in the art to modify Uematsu by having a means for placing the lysis vessels of the lysis unit in a leaned-to position because it is known in the art that a higher degree of sensitivity and reduction in time of reaction can be attained when the vessel is inclined at a certain angle.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

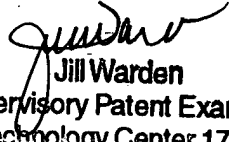
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

Application/Control Number:
10/694,136
Art Unit: 1797

Page 10

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano
Examiner
Art Unit 1797


Jill Warden
Supervisory Patent Examiner
Technology Center 1700